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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,705	02/21/2002	John Barthelow Classen	22499-68466	1273

23973 7590 08/18/2006

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EXAMINER

LEROUX, ETIENNE PIERRE

ART UNIT PAPER NUMBER

2161

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,705	Applicant(s) CLASSEN, JOHN BARTHELOW	
	Examiner Etienne P LeRoux	Art Unit 2161	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 201-213 and 215-251 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 201-213 and 215-251 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Status:

Claims 201-213 and 215-251 are pending: claims 1-200 have been cancelled and claim 214 has been omitted. Claims 201-213 and 215-251 are rejected as detailed below.

Claim Objections

Claims 215 through 246 are objected to because claim 214 has been omitted. Numbering of the claims needs to be addressed.

Claims 247-249 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 247-249 depend from cancelled claim 33.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 201-213 and 215-251 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps of claim 1 are:

- (1) the steps required to analyze the data to identify one new essential adverse event
- (2) the steps required for commercializing of the new adverse event information
- (3) the method of identifying new essential adverse event information for a product or device

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Examiner maintains the scope of the invention is difficult to determine because of the above missing method steps. Claim 201 comprises a preamble with no body in which the invention is positively claimed.

The independent claims of the claimed invention are rejected for at least being dependent from a rejected base claim.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 201-213 and 215-251 of the claimed invention are directed to non-statutory subject matter. The present invention is directed to the judicial exception of natural phenomena. Analyzing possible adverse interactions between drugs and possible adverse interactions between hazardous materials is the consideration of naturally occurring phenomena and thus is not patentable. In particular, Applicant is attempting to preempt the function(s) of the Food and Drug Administration by attempting to obtain a patent for analyzing drug interactions.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

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USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 201 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of U.S. Patent No 6,219,674 (Classen). Although the conflicting claims are not identical, they are not patentably distinct from each other because elements of claim 201 of instant application are fully covered by claim 15 of US Pat No 6,219,674.

Claim 15 of U.S. Patent No 6,219,674 (Classen) contains every element of claim 201 of instant application and thus anticipates the claim of the instant application. Claim(s) of the instant application therefore is/are not patentably distinct from the earlier patent claim(s) and as such is unpatentable over obvious-type double patenting. A later patent/application claim is not patentably distinct from an earlier filed claim if the claim is anticipated by the earlier claim.

Instant Application:

Claim 201 recites:

A method for using data associated with at least one dataset, wherein essential adverse event information is stored, and

wherein the data is derived from an analysis of data from at least one adverse event data source of previously gathered data, and

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identifies at least one new useful characteristic or use for a product or device responsive to identification of at least one new essential adverse event associated therewith, wherein the database comprises stored essential adverse event information, and wherein the adverse event information includes the at least one new use or characteristic,

said method comprising commercializing new essential adverse event information stored therein.

US Pat No 6,219,674:

Claim 15 recites:

15. A method for creating and using product data, said method comprising the steps of:

accessing at least one adverse event data source that stores adverse event data associated with a commercially available product;

analyzing said adverse event data to identify new adverse events associated with the product;

creating at least one adverse event information database, said creating comprising analyzing data from said at least one adverse event data source to identify at least one new use for the product responsive to identification of at least one new adverse event associated with the product, said creating further comprising storing adverse event information, said adverse event information including said at least one new use; and

commercializing adverse event information stored at said at least one adverse event information database.

Response to Arguments

Applicant's arguments with respect to claims 201-246 have been considered but are moot in view of the new ground(s) of rejection. Examiner reviewed applicant's arguments regarding the double-patenting rejection but was not persuaded.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etienne P. LeRoux whose telephone number is (571) 272-4022. The examiner can normally be reached Monday through Friday between 8:00 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Gaffin can be reached on (571) 272-4146. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Etienne LeRoux

8/17/2006



Primary Examiner